UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,505	10/16/2003	Christine Nocl	231893US0	5083

22850 7590 01/29/2007

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,505	NOEL ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Reconsideration filed 10/19/06 and the Rule 132 Declaration/Remarks filed 11/1/07 is acknowledged. Claims **1 and 4-20** are directed to the elected invention. Claims 2-3 and 21-24 are withdrawn as being directed to non-elected invention and species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 6-18, 20 under 35 U.S.C. 103(a) as being unpatentable over WO 02/03952 is maintained.

WO '952 teaches skin care composition comprising silicone elastomers and a skin care active. See abstract. The composition may be in an oil-in-water emulsion. See page 32, lines 15-20 and examples. The composition comprises silicone elastomers in an amount of 1-20%. The organopolysiloxane is preferably an addition reaction curing organopolysiloxane in the presence of a platinum catalyst. The instant organopolysiloxane is taught. See pages 10-14. The carrier for the elastomer serves to suspend and swell the elastomer particles to provide elastic, gel-like matrix. The carrier is utilized in an amount of 5-50% and may be volatile or non-volatile oil. See page 14. The composition further comprises thickening agents including carboxylic acid polymers, polyacrylate polymers, polysaccharides, gums, and instant polyacrylamide polymer (Speigel) in the amount of 0.1-5%. See page 19-22 and particularly page 20, line 30 to page 21, line 7. WO '952 teaches the use of active agents including anti-wrinkles agents such as N-acetyl-

derivatives, for instance N-acetyl-cysteine (see page 46, line 24) and antioxidants such as methionine, proline, or lysine in an amount of 0.1-10% to provide UV protection (see page 48, line 20). The composition may be formulated into facial skin cosmetics, eye cosmetics, anti-wrinkle creams, lip cosmetics, foundations, etc. The composition is useful in reducing the appearance of wrinkles, scars, skin roughness, blemishes, pores, etc.

Although WO '952 teaches the use of lipophilic amino acids such as N-acetyl-cysteine and methionine, the active agents taught by WO '952 are not sufficiently limited for one to immediately envisage the use of the N-acetyl-cysteine, proline, or methionine; thus the rejection is made under obviousness.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to look to the guidance provided by WO '952 and utilize N-acetyl-cysteine or methionine in the composition to provide an o/w emulsion comprising 1) silicone elastomers; 2) a hydrophilic polymer; and 3) a lipophilic amino acid. One would have been motivated to do so since WO '952 teaches the use of N-acetyl-cysteine if one desired to formulate an anti-wrinkle cream and methionine if one desired to formulate a UV protection cream. Therefore, the selection of the active agent is prima facie obvious depending on the desired aesthetic benefit provided by the skin care composition.

Note that claims 7 and 9, have product-by-process limitations and "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product

of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Response to Arguments and Rule 132 Declaration

Applicant argues that the instant claims require the presence of a lipophilic amino acid and Robinson does not teach a lipophilic amino acid. Applicant argues that N-acetyl derivatives of amino acids and the unsubstituted amino acids taught on page 48 are not lipophilic. Applicant argues that Robinson does not teach each and every element of the claim and thus cannot render the instant invention obvious. Applicant argues that Robinson does not teach claim 4.

Applicant's arguments filed 10/19/06 and 11/1/06 have been fully considered but they are not persuasive. Firstly, the examiner points out that claim 4 is not rejected over Robinson. The examiner acknowledges that Robinson does not teach the limitations of claims 4 and 5; thus claims 4-5 are rejected over Robinson in view of FR 2771632 or US '257.

With regard to claims 1, 6-18, and 20, the examiner points out that claim 1 is broadly directed to a "lipophilic amino acid or salt thereof". The specification does not provide a definition of "lipophilic amino acid". Thus, the claims are not limited to an amino acid that is linked to a fatty acid. As acknowledged by applicant, Robinson teaches the preferred use of N-acetyl-cysteine on page 46, line 24 as an anti-wrinkle active. On page 48, line 20, Robinson teaches the use of methoinine or proline as antioxidants. Applicant argues that N-acetyl-cysteine, methoinine, nor proline are lipophilic. The examiner respectfully disagrees.

US 5,874,086 discloses, "Lipophilic amino acid (Laa)" refers to an uncharged, aliphatic or aromatic amino acid, such as isoleucine, leucine, methionine, phenylalanine, tryptophan, tyrosine, valine, and their homologs." See column 7, lines 60-65.

US 6,653,280 discloses, "neutral nonpolar (hydrophobic) amino acids such as alanine, leucine, isoleucine, valine, proline, phenylalanine, tryptophan, and methionine" see example 5.

US 5,192,747 discloses, "The term "lipophilic amino acid" includes Tyr, Phe, Leu, Met, Nle, Ile, Val, and Pro." See column 4, lines 60-63.

US 20030141260 discloses, "Suitable lipophilic antioxidants include cysteine derivatives such as N-acetyl-L-cysteine, N-acetyl-D-cysteine (NAC), glutathione (GSH), L-cysteine,..". see [0084].

Thus, it is the examiner's position that Robinson teaches lipophilic amino acids since the art considers methionine and N-acetyl-cysteine as a lipophilic compounds.

The Declaration under 37 CFR 1.132 filed 11/1/06 is insufficient to overcome the rejection of claims 1, 6-18, and 20 based upon Robinson as set forth in the last Office action because: The Declaration attempts to demonstrate that the use of a lipophilic amino acid, specifically undecylenolyglycine, provides for a stable emulsion whereas as a emulsion without the lipophilic amino acid is unstable. This instability is characterized by the presence of "large oily globules throughout". Firstly, the examiner points out that the independent claims are directed to "lipophilic amino acids or salt thereof" and the Declaration demonstrates the "unexpectedness" of a *single species*. The unexpectedness of a single species, i.e. undecylenolyglycine, does not establish the unexpectedness of an entire genus, i.e. "lipophilic amino acids and salt thereof". Thus, the claims are not commensurate in scope.

Secondly, it is noted that applicant has not made a comparison with the closest prior art. A proper comparison would be a comparison of Robinson's lipophilic amino acid (methionine or N-acetyl-cysteine) and the instant lipophilic amino acid.

Thirdly, the examiner points out that the claims are directed to an "oil-in-water emulsion wherein the oily phase is dispersed in a aqueous phase". The claims do not specify the size of the oil droplets (globules). Meaning the claims do not require small oil globules. The examiner points out that the mere statement that the comparative compositions are unstable dispersions since they "hav[e] large oily globules throughout" and the instant composition is a fine dispersion is not enough to establish the unexpectedness of the instant invention since applicant has not provided the oil droplet size in terms of a numerical value for the examiner to compare. Applicant is merely uses relative terms such as "large globules" versus "fine dispersion". Therefore, the examiner cannot make a conclusive determination of the purported unexpectedness of the instant invention.

The rejection of claims 4-5 under 35 U.S.C. 103(a) as being unpatentable over WO 02/03952 in further view FR 2771632 to Stoltz or US 20010002257 (English equivalent) is maintained.

The teachings of WO '952 have been set forth above. In particular, WO '952 teaches the use of active agents including anti-wrinkles agents such as N-acetyl-derivatives, for instance N-acetyl-cysteine (see page 46, line 24), acne actives, and skin soothing agents.

The reference does not teach the instant lipoamino acid.

Stoltz teaches the use of N-acyl amino acids for formulating cosmetic compositions that provides soothing/protecting properties, retards skin aging, and provides disinfecting properties to treat acne. The amino acids taught are undecylenoyl glycine and octanoyl glycine. See abstract.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of WO '952 and Stoltz and utilize the instantly claimed amino acid. One would have been motivated to do so since Stoltz teaches the undecylenoyl glycine and octanoyl glycine provides soothing/protecting properties, retards skin aging, provides disinfecting properties to treat acne and WO'952 teaches anti-wrinkles agents such as amino acid derivatives, the use of antioxidants such as methionine, acne actives, and soothing/skin healing actives. Thus, a skilled artisan would have been motivated to utilize the instant amino acid to provide a cosmetic composition that provides all three skin benefits of treating acne, retarding aging, and soothing the skin in a single formulation. A skilled artisan would have expected success since Stoltz teaches the use of various skin active agents including lipoamino acids.

Response to Arguments and Rule 132 Declaration

Applicant argues that Stolz does not compensate for the deficiencies of Robinson. Applicant argues that there is not motivation to combine the references with the primary references with the expectation that a stable emulsion would result.

Applicant's arguments filed 10/19/06 and 11/1/06 have been fully considered but they are not persuasive. The merits of Robinson has discussed above. The examiner points out that the motivation to combine the references do not need to be the same as applicant's since the combination provides the same product claimed. As set forth in the rejection, the motivation to utilize the instant amino acids is for the advantages taught by Stolz. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

With regard to the Rule 132 Declaration, note the discussion above. Briefly, the examiner points out that claim 4 is directed to "glycine derivatives" and the declaration only provides the results of one species, undecylenoylglycine. Claim 5 is directed to capryloylglycine or undecylenoylglycine. It is unclear if the length of the fatty chain affects the stability. For instance, if the glycine derivative has a shorter chain fatty acid compared to a derivative with a long chain fatty acid, would the results pertaining to stability be the same? Again, the unexpectedness of a single species does not demonstrate the unexpectedness of an entire genus. Therefore, the claims are not commensurate in scope. Additionally as discussed above, applicant has not provided any data pertaining to the oil droplet sizes and merely provides relatives terms. Thus, the examiner cannot make a conclusive determination of the purported stability.

The rejection of claims 1 and 4-20 under 35 U.S.C. 103(a) as being unpatentable over EP 1055406 or US 6,296,859, the English equivalent in view of Fotinos (6,346,255) is maintained.

Lorant teaches an oil-in-water emulsion comprising an organopolysiloxane elastomer in the oily phase and a water-soluble polymer in the aqueous phase. The oil-in-water emulsions are stable and thus do not contain a conventionally used surfactant. Lorant teaches emulsifiers are potentially irritating the skin, eyes and scalp and thus it is advantageous to formulate an emulsion without using emulsifiers to stabilize the emulsion. The compositions provide fresh and comfortable during application to the skin, unlike conventional compositions. See abstract and column 1, lines 18-36. Lorant teaches the use of α, ω dimethylvinylpolydimethylsiloxane. See column 4, line 50 and the elastomer gel is utilized in an amount of 0.03-40% and preferably 1.5-20%. See column 5, lines 59-66. The water-soluble polymers that are suitable include

carboxyvinyl polymers; acrylic or methacrylic copolymers; natural gums; polysaccharides; acrylamide polymers and copolymers; vinyl ether copolymers; or cationic polymers, such as polyquaternium. Preferable acrylamide copolymers include the crosslinked copolymer of acrylamide and of 2-acrylamido-2-methylpropanesulphonic acid, in particular the mixture sold under the name Sepigel 305. The polymer is utilized in the an amount from 0.1 to 10%, preferably 0.2 to 5%, and more preferably from 0.5 to 2%. See column 6, line 5 to column 9, line 40. The oils utilized in the oil phase include non-volatile and volatile oils and the oily phase can range from 1 to 50%. See column 9, line 40 to column 10, line 25. The composition comprises active agent in the amount of 0.01-30% and may be antioxidants, lipophilic active agents, etc. Preferably the active agents include moisturizing agents; keratolytic agents; salicylic acid and its derivatives; vitamins; depigmenting agents; slimming agents; screening agents; and any active principle appropriate for the final purpose of the composition. see column 10, lines 32-60. The composition suitable for treating dry skin and/or dry lips. See column 11, lines 1-7.

Lorant does not teach the use of the instant lipophilic amino acids.

Fotinos teaches improving skin appearance with akin permeation enhancer and a active agent. See abstract. Fotinos teaches the use of various lipoamino acids such as acylation products, which are anti-elastase and anti-collagenase agents (anti-wrinkle agents); the use of lipoamino acids such as lysine and lauroylmethionine as antioxidants; lipoamino acids such as instant capryloyl glycine as seboregulators; lipoamino acids such as lysine PCA and related compound as hydratives. See column 7, lines 36-65.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Lorant and Fotinos and utilize lipoamino acids as the active

agent in Lorant's composition. One would have been motivated to do so since Fotinos teaches lipoamino acids have a large number of applications in the cosmetic field including anti-wrinkle agents, antioxidants, hydrating agents, and seboregulators and Lorant teaches the use of any skin active agent including antioxidants and moisturizing agents, depending on the final purpose of the composition. Therefore, the selection of the active agent is prima facie obvious depending on the desired aesthetic benefit provided by the skin care composition. Furthermore, a skilled artisan would have been motivated to utilize capryloyl glycine in particular if one desired to provide a composition that controls sebum, which causes acne.

Response to Arguments and Rule 132 Declaration

Applicant argues that Lorant does not teach or suggest the claimed lipophilic amino acids. Applicant argues that Fontinos does not compensate for Lorant's deficiencies. Applicant argues that there is not motivation to combine the references with the primary references with the expectation that a stable emulsion would result.

Applicant's arguments filed 10/19/06 and 11/1/06 have been fully considered but they are not persuasive. Firstly, it is noted that Lorant does not teach a lipophilic amino acid; thus, the examiner relies on Fontinos to cure this deficiency. Lorant suggests the use of antioxidants, moisturizers, and other lipophilic actives as the cosmetic benefit agent. Fontinos teaches lipoamino acids such as lysine and lauroylmethionine as antioxidants; lipoamino acids such as instant capryloyl glycine as seboregulators; lipoamino acids such as lysine PCA as hydratives. Therefore, for instance, a skilled artisan would have been motivated to utilize lauroylmethionine as the antioxidant of choice if one desired to provide a anti-aging. Similarly, a skilled artisan would have been motivated to utilize capryloyl glycine if one desired to provide a composition

that controls sebum. Applicant has not addressed the examiner's motivation. The examiner points out that the motivation to combine the references need not be the same as applicant's since the combination provides the same product.

The Declaration under 37 CFR 1.132 filed 11/1/06 is insufficient to overcome the rejection of claims 1 and 4-20 based upon EP 1055406 or US 6,296,859, the English equivalent in view of Fontinos (6,346,255) as set forth in the last Office action because: The Declaration attempts to demonstrate that the use of a lipophilic amino acid, specifically undecylenolyglycine, provides for a stable emulsion whereas as a emulsion without the lipophilic amino acid is unstable. This instability is characterized by the presence of "large oily globules throughout". Firstly, the examiner points out that the independent claims are directed to "lipophilic amino acids or salt thereof" and the Declaration demonstrates the "unexpectedness" of a *single species*. It is unclear if the length of the fatty chain affects the stability. For instance, if the glycine derivative has a shorter chain fatty acid compared to a derivative with a long chain fatty acid, would the results pertaining to stability be the same? The unexpectedness of a single species, i.e. undecylenolyglycine, does not establish the unexpectedness of an entire genus, i.e. "lipophilic amino acids and salt thereof". Thus, the claims are not commensurate in scope.

Secondly, the examiner points out that the claims are directed to an "oil-in-water emulsion wherein the oily phase is dispersed in a aqueous phase". The claims do not specify the size of the oil droplets (globules). Meaning the claims do not require small oil globules. The examiner points out that the mere statement that the comparative compositions are unstable dispersions since they "hav[e] large oily globules throughout" and the instant composition is a fine dispersion is not enough to establish the unexpectedness of the instant invention since

applicant has not provided the globule size in terms of a numerical value for the examiner to compare. Applicant is merely uses relative terms such as "large globules" versus "fine dispersion". Therefore, the examiner cannot make a conclusive determination of the purported unexpectedness of the instant invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Examiner
Art Unit 1616